UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,020	08/14/2001	Kurt C. Gish	018501-003100US	2304

20350 7590 02/11/2003

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,020	GISH ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *election facsimile cover sheet* .

DETAILED ACTION

1. Claims 1-31 are currently pending in the application and are subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1 and 2, insofar as the claims are drawn to a method for screening drug candidates, said method comprising contacting a cell with a candidate drug and determining the effect of said candidate drug on the expression of one of the expression profile genes, or a fragment thereof, listed in Tables 1 or 2 of the specification, classified in class 435, subclass 377.

Note: If claims 1 and 2 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the expression profile genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 3 and 4, insofar as the claims are drawn to a method for screening bioactive agents for the capability to bind and/or modulate the activity of a polypeptide encoded by one of the expression profile genes, or a fragment thereof, listed in Tables 1 or 2 of the specification, said method comprising contacting protein with a candidate bioactive agent, classified in class 435, subclass 7.23.

Note: If claims 3 and 4 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the expression profile genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 5 and 6, insofar as the claims are drawn to a method for evaluating the effect of a candidate drug, said method comprising administering said candidate drug to a patient and determining the effect by measuring the expression of one of the genes listed in Tables 1 or 2 of the specification, classified in class 424, subclass 9.2.

Note: If claims 5 and 6 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the expression profile genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 7, insofar as the claim is drawn to a method for diagnosing colorectal cancer, said method comprising determining the expression of one or more of the genes listed in Tables 1 or 2 of the specification, classified in class 424, subclass 9.1, class 435, subclass 6, or class 435, subclass 7.23.

Note: If claim 7 is to be examined, Applicant is required to elect a single invention drawn to one (1) specific combination consisting of one or more of the genes listed in Table 1 or Table 2 of the specification.

Please identify the elected invention by specifically indicating to which combination of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 8, insofar as the claim is drawn to a method for screening bioactive agents for the capability of interfering with the binding of an antibody to a polypeptide encoded by one of the expression profile genes, or a fragment thereof, listed in Tables 1 or 2 of the specification, said method comprising contacting said polypeptide and said antibody with a candidate bioactive agent, classified in class 435, subclass 7.23.

Note: If claim 8 is to be examined, Applicant is required to elect a single invention drawn to one (1) of the expression profile genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 9, 10, and 13, insofar as the claims are drawn to a method for inhibiting or neutralizing the activity or effect of a polypeptide encoded by one (1) of the nucleic acid molecules, or a fragment thereof, listed in Table 1 or Table 2 of the specification, which cannot be classified because the nature of the inhibitor is not disclosed.

Note: If claims 9, 10, and 13 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of

the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 11, 12, 14-16, and 29-31, insofar as the claims are drawn to a method for treating a patient diagnosed with colorectal cancer, said method comprising administering to the patient an inhibitor of the polypeptide encoded by one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification, classified in class 424, subclass 1.49 and/or 138.1.

Note: If claims 11, 12, 14-16, and 29-31 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 17, insofar as the claim is drawn to a method for inhibiting colorectal cancer, said method comprising administering a composition comprising antisense molecules to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification, classified in class 424, subclass 93.21.

Note: If claim 17 is to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 18-21, insofar as the claims are drawn to an antibody that specifically binds a polypeptide encoded by one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification, classified in class 530, subclass 387.1 or 388.1.

Note: If claims 18-21 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 22, insofar as the claim is drawn to a biochip comprising one or more of the nucleic acid segments listed in Table 1 or Table 2 of the specification, classified in class 536, subclass 24.31.

Note: If claim 22 is to be examined, Applicant is required to elect a single invention drawn to one (1) specific combination consisting of one or more of the genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which combination of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 23 and 24, insofar as the claims are drawn to a nucleic acid having a sequence that is at least 95% homologous to one (1) of the nucleic acid molecules, or its complement, listed in Table 1 or Table 2 of the specification, classified in class 536, subclass 23.5.

Note: If claims 23 and 24 are to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid

molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 25, insofar as the claim is drawn to a polypeptide encoded by one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification, classified in class 530, subclass 350.

Note: If claim 25 is to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 26, insofar as the claim is drawn to a method of eliciting an immune response in an individual, said method comprising administering to the individual a composition comprising a polypeptide or a fragment thereof encoded by one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification, classified in class 424, subclass 277.1.

Note: If claim 26 is to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claims 27, insofar as the claim is drawn to a method of eliciting an immune response in an individual, said method comprising administering to the individual a composition comprising one (1) of the nucleic acid molecules, or a fragment thereof, listed in Table 1 or Table 2 of the specification, classified in class 514, subclass 44.

Note: If claim 27 is to be examined, Applicant is required to elect a single invention drawn to one (1) of the nucleic acid molecules listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which of the nucleic acid molecules in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

Claim 28, insofar as the claim is drawn to a method for determining the prognosis of an individual with colorectal cancer, said method comprising determining the expression of one or more of the genes listed in Table 1 or Table 2 of the specification, classified in class 435, subclass 6.

Note: If claim 28 is to be examined, Applicant is required to elect a single invention drawn to one (1) specific combination consisting of one or more of the genes listed in Table 1 or Table 2 of the specification. Please identify the elected invention by specifically indicating to which combination of the genes in Table 1 or Table 2 the claims are to be drawn for purposes of examination.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of claims 18-21, claim 22, claims 23 and 24, and claim 25 are biologically and chemically distinct molecules comprising distinct

polynucleotide sequences that encode biologically and chemically distinct proteins with unique amino acid sequences and are therefore distinct inventions.

The inventions of claims 1 and 2, claims 3 and 4, claims 5 and 6, claim 7, claim 8, claims 9, 10, and 13, claims 11, 12, 14-16, and 29-31, claim 17, claim 26, claim 27, and claim 28 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

The inventions of claims 18-21 and the inventions of claim 8 and claims 11, 12, 14-16, and 29-31 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case product as claimed, namely the antibody can be used in a materially different process of using that product, such as affinity chromatography.

The inventions of claim 25 and the inventions of claims 3 and 4, claim 8, claims 9, 10, and 13, and claim 26 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as in the process of producing a reagent antibody that binds the polypeptide.

The inventions of claims 23 and 24 and the inventions of claim 17 and claim 27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such as producing the polypeptide encoded by the nucleic acid molecule.

The invention of claims 18-21 and the inventions of claims 1-7, 9, 10, 13, 17, and 26-28 are not at all related because the products of claims 18-21 are not specifically used in any of the steps of the one of the methods of claims 1-7, 9, 10, 13, 17, and 26-28.

The invention of claims 23 and 24 and the inventions of claims 1-16, 26, and 28-31 are not at all related because the products of claims 23 and 24 are not specifically used in any of the steps of the one of the methods of claims 1-16, 26, and 28-31.

The invention of claim 25 and the inventions of claims 1, 2, 5-7, 11, 12, 14-17, and 27-31 are not at all related because the product of claim 25 is not specifically used in any of the steps of the one of the methods of claims.

The invention of claim 22 and the inventions of claims 1-17 and 26-31 are not at all related because the product of claim 22 is not specifically used in any of the steps of the one of the methods of claims 1-17 and 26-31.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 6, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.

COMMENTS: _____

_____

_____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096-OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.